



K03 3412

DEC 3 0 2003

Appendix E

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

This summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92( c ).

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**Submitted by:**

*Name:* Medicsight PLC.

*Address:* 46 Berkeley Square  
London W1J 5AT  
UK

*Telephone:* 44 (0) 207 598 4070

*Facsimile:* 44 (0) 207 598 4071

*Contact:* Carol MacDonald, RA QA Manager

*Date of summary:* 22 September 2003

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**Device Information:**

*Trade Name:* MedicLung™ Release 1

*Common Name:* Medical imaging software for CT scanners

*Classification Name:* Computed Tomography X-Ray System, Accessory

*Regulation Number:* 892.1750

**Predicate Devices:**

Medicsight MedicLung 1 is substantially equivalent to the following devices:

<u>Manufacturer</u>	<u>Device</u>	<u>510(k) No.</u>
GE	GE ADVANCED LUNG ANALYSIS-I	K013381
SIEMENS	LUNGCARE CT SOFTWARE PACKAGE	K022013



### **Device Description:**

K037412

MedicLung™ 1 is a software tool designed to assist radiologists and other clinicians in the evaluation of nodules and other lesions in the lung. The software allows the user to select Regions of Interest either manually or by selecting a single or double seed point, followed by semi-automatic detection of the ROI boundary. It provides 2D and 3D visualisation of nodules and other lesions, and measurement of nodule characteristics such as size and volume.

### **Intended Use:**

MedicLung I is a PC-based, stand-alone, non-invasive, image analysis software application for the display and visualization of 2D and 3D medical image data of the lung derived from CT scans, for the purpose of assisting radiologists and other clinicians in the evaluation of lung lesions (e.g. nodules). The software provides functionality for the user to extract the region of interest (ROI) either manually using a drawing tool, or “semi-automatically” through the user selecting either a single or double seed point followed by interactive fine-tuning the boundaries of the ROI. MedicLung I provides quantitative information for measurement of lesion volume and other measured characteristics over time allowing the user to review and track any changes in the physician-indicated nodules or lesions.

### **Comparison to Predicate Device:**

As in the predicate devices, GE Advanced LungAnalysis-1 and Siemens LunCareCT, MedicLung I assists users in assessing CT images for the identification and evaluation of nodules and other lesions in the lung.

Test data are provided to validate the performance of the system and its substantial equivalence to the predicate devices. The functional features and the intended use of MedicLung I are substantially equivalent to the predicate devices.

### **Safety:**

A comprehensive hazard analysis was carried out on MedicLung 1, which concluded that any residual risks were as low as reasonably practicable and judged as acceptable when weighed against the intended benefits of use of the system.

### **Conclusion:**

MedicLung 1 does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices. MedicLung 1 is therefore substantially equivalent with respect to safety and effectiveness to the predicate devices.



DEC 3 0 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Carol MacDonald  
Regulatory & Quality Manager  
Medicsight  
46 Berkeley Square  
London, W 1J 5AT  
UNITED KINGDOM

Re: K033412  
Trade/Device Name: Medicsight MedicLung 1.0  
Regulation Number: 21 CFR 892.1750  
Regulation Name: Computed tomography  
x-ray system  
Regulatory Class: II  
Product Code: 90 JAK  
Dated: October 24, 2003  
Received: November 5, 2003

Dear Ms. MacDonald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

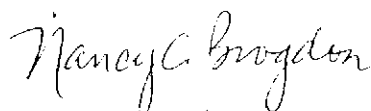
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K03 3412Device Name: Medicsight MedicLung 1.0

## Indications for Use:

MedicLung I is a PC-based, stand-alone, non-invasive, image analysis software application for the display and visualization of 2D and 3D medical image data of the lung derived from CT scans, for the purpose of assisting radiologists and other clinicians in the evaluation of lung lesions (e.g. nodules). The software provides functionality for the user to extract the region of interest (ROI) either manually using a drawing tool, or "semi-automatically" through the user selecting either a single or double seed point followed by interactive fine-tuning the boundaries of the ROI. MedicLung I provides quantitative information for measurement of lesion volume and other measured characteristics over time allowing the user to review and track any changes in the physician-indicated nodules or lesions.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON  
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒

Nancy C Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K033412